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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,485	06/06/2001	Steven Leigh	032553-011	5205

21839 7590 04/23/2003

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,485

Applicant(s)

Leigh

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 27, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-14, 16-25, 27-37, and 39-47 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-14, 16-25, 27-37, and 39-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The request for the extension of time and amendment dated 1-27-03 are acknowledged.

Claims 1-4, 15, 26 and 38 have been canceled by applicant. Claims pending are 5-14, 16-25, 27-37 and 39-47.

Claim Rejections - 35 USC § 112

1.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what applicant intends to convey by ‘the diacylphospholipid obtained by enzyme digestion of lecithin as recited in the amended claim 5. Lecithin is a diacylphospholipid since it has two acyl groups. How can a diacylphospholipid form by the enzymic digestion of another diacylphospholipid such as lecithin?

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 5, 7-14, 16-19, 31-39, 42-43 and 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Leigh 5,141,674.

Leigh discloses liposomal powders containing a hydrophobic drug and a lipophilic medium and a polymer such as starch and dextran. The liposomes are made of glycolipids or mono and dialkyl polyoxyethylene derivative or two grades of soybean lecithin (note the abstract, col. 3, line 13 through col. 4, line 25, Example IV and claims). It is known in the art that commercially available lecithins contain lysophospholipids. The examiner cites US 6,303,803 in this context. The examiner also points out that sphingosine (monoacyl compound) containing a sugar residue is a glycolipid.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant point out to col. 4, lines 16-17 of Leigh and argues that Leigh requires that the solid carrier must not be soluble in the solvent and therefore, teaches away. This argument is not found to be persuasive since according to claim 39, the organic solvent or organic solvent mixture is removed from a homogeneous dispersion containing

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the polymeric material and according to claim 43, it is 'forming a homogenous dispersion' containing the polymeric material (see lines 3 and 4 of claim 43). This indicates that even in instant invention, the solid carrier is not soluble in the solvent.

Applicant while admitting that naturally occurring is known to contain lyso-compounds, argue that these are present only in small quantities and as impurities. This argument is not found to be persuasive since instant claims do not recite any specific amounts of the lyso compounds and therefore, the prior art preparations which applicant himself admits to contain small amounts of lyso compounds, read on instant claims.

Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 5-14, 16-19, 31-39, 42-43 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leigh (5,141,674) in view of Huang (5,043,164), Baumann (5,009,956) individually or in combination.

Leigh as pointed out above, discloses liposomal powders containing a polymer and a hydrophobic active agent. The liposomes are also made from two grades of lecithin (note the abstract, col. 3, line 13 through col. 4, line 25, Example IV and claims). Although as

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pointed out above, Lecithins are known to be impure mixtures of phospholipids including lyso compounds, Leigh does not specifically teach lysophospholipids.

Huang teaches that micelle forming amphiphiles, lysophospholipids stabilize the liposomes (note the claims).

Baumann teaches lysophospholipids prevent liposomal cleavage by phospholipase A and stabilize the liposomes (note the abstract and claims).

The use of lysolipids or the addition of lysolipids in the teachings of Leigh would have been obvious to one of ordinary skill in the art since Huang and Baumann teach the advantages of using the lysolipids. The criticality of specific drugs recited in instant claims is not readily apparent to the examiner since the novelty of the composition rests in the components it would have been obvious to one of ordinary skill in the art to use any drug with a reasonable expectation of success.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments with regard to Leigh have been addressed above.

Applicant argues that Huang, and Baumann teach that the lysolipids stabilize the liposomes and that the claimed invention however, is not concerned with the formation of liposomes. This argument is not found to be persuasive since applicant's intent to include bilayer structures (liposomes) is clear from the specification on page 5, lines 20-21, page 6, line 32 and page 8, line 32. Furthermore, the motivation to add a lysolipid need not be the same as applicant's.

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11. Claims 5-14, 16-25, 27-37 and 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 7291854 (XP-002136413) of record in view of Huang (5,043,164), Baumann (5,009,956) individually or in combination.

JP teaches a method of preparation of a polymeric product containing a drug, a hydrophilic polymer such as a carbohydrate and lecithin using a solvent system which is either water or water and organic solvent and drying the product (note the abstract). What is lacking in JP is the use of a lysolipid (monacylphospholipid).

Huang teaches that micelle forming amphiphiles, lysophospholipids stabilize the liposomes (note the claims).

Baumann teaches lysophospholipids prevent liposomal cleavage by phospholipase A and stabilize the liposomes (note the abstract and claims).

The use of lysolipids or the addition of lysolipids in the teachings of JP would have been obvious to one of ordinary skill in the art since Huang and Baumann teach the advantages of using the lysolipids. The criticality of specific drugs recited is unclear since JP is drawn to sparingly soluble drugs and one would expect similar results with any sparingly soluble drug.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

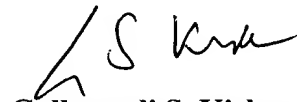
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

A handwritten signature in black ink, appearing to read 'S Kishore', with a stylized flourish at the beginning.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

April 18, 2003